Saltiel

Serial No.: 10/649,287

Filed: **August 27, 2003**

REMARKS

Applicant greatly appreciates the Examiner's continuing careful review of the application. The following remarks are respectfully offered in support of the patentability of the pending claims. The claim amendments and these remarks focus on the pending independent claims since, if these are found patentable, their respective dependent claims will be patentable as well.

Applicant does appreciate the withdrawal by the Examiner of a number of concerns in response to the previously filed arguments. Applicant's responses set forth below are cross-referenced to the Office action by page and paragraph number so that they may be more easily followed.

The Objections To The Claims Have All Been Addressed

On page 7, the examiner objects to claims 6, 17 and 18 for various minor wording issues. Applicant appreciates the Examiner's picking up these small deficiencies in wording and has amended these three claims by adopting the Examiner's suggestions. Accordingly, these objections should now be withdrawn.

The Claims Are Fully Supported Under Section 112

On page 7, paragraph Roman numeral I, the Examiner expresses his concern that the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor had possession of the claimed invention at the time the application was filed. Applicant respectfully disagrees for the following reasons.

First, at least a portion of the description provided in the present application originates from a scientific paper published by Applicant and others in the *Journal of the*

Saltiel

Serial No.: 10/649,287

Filed: **August 27, 2003**

American Chemical Society (JACS), 2003, 125, 2866-2867. That scientific publication not only describes the claimed invention and forms the body of the parent application to which the present application claims priority (US Provisional Application Serial No. 60/407,137 but is also incorporated by reference in the present application at page 21, line 29, through page 22, line 2. Applicant respectfully points out that JACS is a peer-reviewed journal which requires that any article to be published therein be first reviewed by peers having at least ordinary skill in the chemical arts to which the article pertains and be approved for publication by an editor of the journal who is also skilled in the chemical arts to which the article pertains. A copy of the published article is enclosed as Exhibit A for the Examiner's information.

The present application as filed, as well as the published article noted above, leave no doubt that the claimed invention does not require a photosensitizer. The two-step irradiation processes are the "two strategies" discussed beginning on page 20, line 16 of the original patent application. The skilled would know that "a triplet energy donor" (page 20, line 19) is a photosensitizer. Furthermore, the words "direct excitation" (page 20, line 21) indicate that these are processes without a photosensitizer. Thus, the two strategies discussed starting on page 20, line 16, differ in that one is with and the other is without a photosensitizer in the second step. For the Examiner's information, Applicant points out that a useful photosensitizer absorbs essentially all the incident light, efficiently forms a triplet state and then transfers the triplet excitation to the reactant (in the present case, tachysterol). In the photosensitized reaction, it is the photosensitizer that absorbs the light. The reactant absorbs no light and, accordingly, it is not directly excited.

The application as filed specifically addresses the disadvantages of the Malatesta et al. and the Dauben and Phillips approaches starting on page 20, line 26, to wit: "Unfortunately, the second wavelengths that have been suggested are barely absorbed by

Saltiel

Serial No.: 10/649,287

Filed:

August 27, 2003

Tachy and in addition, the desired selective excitation advantage is almost lost." (emphasis added; the second wavelengths being those used in the second direct excitation steps).

Applicant herewith encloses a Declaration under 37 CFR 1.132 wherein the above explanation is contained. Applicant requests that same be entered in the present application as evidence of adequate support for the claims under Section 112 and further requests that the Examiner rejections on that basis be withdrawn.

The Claims Are Novel Over The Cited References

The Examiner has rejected a number of claims as lacking novelty and as being unpatentable under 35 USC §102. Respectfully, Applicant disagrees for the following reasons.

On page 3, paragraph Roman numeral III, the Examiner rejects independent claim 24 as lacking novelty over the Stevens reference (US 4,686,023). As recognized by the Examiner at page 13, "the method of Stevens differs from the instant invention because Stevens does not disclose the following: a. wherein the reaction mixture contains essentially no photosensitizer, as recited in claim 11." Claim 24 has been amended to more clearly recite that the reaction mixture includes no photosensitizer in both the first and second irradiations steps. Since Stevens does not teach a reaction mixture without sensitizer, claim 24 is clearly novel over the Stevens reference and Applicant requests that the Examiner withdraw this rejection.

The Examiner has also rejected independent claim 6 at page 10, paragraph Roman numeral I, as lacking novelty over the reference by Malatesta et al. (US 4,388,242). In this regard, the Examiner has also recognized that Malatesta teaches irradiating a reaction mixture in a second irradiation step with light having a wavelength of between 330-360 nm (see at Malatesta, column 1, lines 58-65). However, the Examiner appears to be alleging

Saltiel

Serial No.: 10/649,287

Filed: **August 27, 2003**

that a second irradiation step with light having a wavelength of from 300-330 nm is equivalent to the range of Malatesta, which is 330-360 nm.

Applicant believes the Examiner is pointing to the minor overlap in these ranges at 330 nm and has, accordingly, amended all claims which may be affected by this concern to recite a wavelength range in the second irradiation of from approximately 300 to less than 330 nm. In this regard, Applicant points specifically at FIG. 8 in the application as filed, which clearly shows that at 330 nm or above, the compounds of interest absorb negligible amounts of light energy, rendering irradiation at those wavelengths highly inefficient. Since FIG. 8 teaches that there is little or no absorption of light energy at 330 nm or above, Applicant believes there is ample support in the application as filed for this claim recitation.

As Malatesta fails to teach a second irradiation step at a wavelength between 300 and less than 330 nm, Applicant asserts that independent claim 6 is novel over the cited reference and requests that the rejection for lack of novelty be withdrawn.

The same reasoning applies to independent claim 11 (rejected at page 10, paragraph Roman numeral II) and independent claim 24 (rejected at page 11, paragraph Roman numeral III). The same clarifying amendment has been made in these two claims and, for the reasons noted above, Applicant respectfully requests that the Examiner withdraw the rejections under Section 102.

Claims 11 And 16 Are Nonobvious And Patentable Over The Stevens Reference

On page 12, paragraph Roman numeral I, independent claims 11 and 16 are rejected under 35 USC §103(a) as unpatentable over Stevens (US 4,686,023). Applicant respectfully disagrees for the following reasons.

With regard to claim 11, the Examiner has previously recognized that the Stevens reference fails to teach wherein the reaction mixture contains essentially no

Saltiel

Serial No.: 10/649,287

Filed: **August 27, 2003**

photosensitizer. Claim 11 has been amended to recite more clearly that there is substantially no photosensitizer in the reaction mixture and in the first and second irradiations. Additionally, claim 11 has been amended to recite "substantially no photosensitizer," so that the Examiner's concerns regarding the use and implications of the word "essentially" are now moot.

Claim 16 recites "estimating progress of the process by applying singular value decomposition analysis to the monitored ultraviolet spectrum of the reaction mixture compared to the ultraviolet spectra for provitamin D, previtamin D, vitamin D, lumisterol, and tachysterol." Stevens is silent in this regard and teaches nothing regarding monitoring the progress of the reaction process by this method. Accordingly, the Stevens reference cannot render the invention of claim 16 obvious. It is of no import that Stevens teaches that Dauben reported maximizing yield of vitamin D by using a second irradiation with light of a wavelength of 330 nm or greater. Claim 16 is a method for monitoring the progress of the reaction, not a method of producing vitamin D and is not made obvious by references which do not teach "applying singular value decomposition analysis to the monitored ultraviolet spectrum of the reaction mixture."

For those reasons, Applicant respectfully requests that the rejection of independent claims 11 and 16 be withdrawn.

Claims 1, 16 And 18 Are Nonobvious Over The Malatesta Reference

On page 17, paragraph Roman numeral III, the Examiner rejects claim 1 as unpatentable under 35 USC §103(a) in view of the Malatesta reference (US 4,388,242). Claim 16 is similarly rejected on page 21, at paragraph VIII, and claim 18 is likewise rejected at page 23, paragraph IX. Applicant respectfully disagrees for the following reasons.

Saltiel

Serial No.: 10/649,287

Filed: **August 27, 2003**

August 27, 2003

As noted above, claims 1, 16 and 18 have been amended to recite that the second irradiation step is conducted with light having a wavelength of from about 300 to less than 330 nm. Applicant has pointed at least to present FIG. 8 for support and for showing that in the present system the compounds of interest demonstrate near zero, if not zero, absorption of light energy at these wavelengths. Malatesta fails to teach absorption at wavelengths below 330 nm in the second irradiation step and, therefore, cannot make the claimed invention obvious.

For those reasons, Applicant respectfully requests that the Examiner withdraw the rejections of claims 1, 16 and 18 under Section 103.

Conclusion

In view of the amendments and the remarks presented herein, it is submitted that these claims are patentable. In addition, their respective dependent claims, which recite yet further distinguishing features, are also patentable and require no further consideration.

If the further prosecution can be facilitated through a telephone conference between the Examiner and the undersigned, the Examiner is respectfully requested to telephone the undersigned at her convenience.

Respectfully submitted

Enrique G. Estévez

Reg. No. 37,823

Allen, Dyer, Doppelt, Milbrath & Gilchrist, P.A.

255 S. Orange Ave., Suite 1401

P. O. Box 3791

Orlando, Florida 32802

(407) 841-2330

In re Patent Application of:
Saltiel
Serial No.: 10/649,287
Filed: August 27, 2003

CERTIFICATION OF FILING VIA U.S. EXPRESS MAIL

I hereby certify that the foregoin is being filed in the U.S. Patent and Trademark Office via U.S. Express Mail No. EV366742355US in an enveloped addressed to Mail Stop Amendments, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 this 10th day of March, 2006.